

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 06-113-JJF
	:	(Consolidated)
DEY L.P. and DEY, INC.,	:	
	:	
Defendants.	:	

Joseph M. O'Malley, Jr., Esquire and Bruce M. Wexler, Esquire of
PAUL, HASTINGS, JANOFSKY & WALKER LLP, New York, New York.

Jack B. Blumenfeld, Esquire; Karen Jacobs Loudon, Esquire and
Andrew C. Mayo, Esquire of MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
Wilmington, Delaware.

Attorneys for Plaintiff.

Edgar H. Haug, Esquire and Sam V. Desai, Esquire of FROMMER,
LAWRENCE & HAUG LLP, New York, New York.

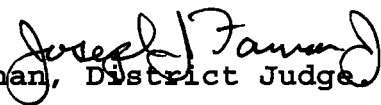
Elizabeth A. Leff, Esquire of FROMMER, LAWRENCE & HAUG LLP,
Washington, D.C.

Steven J. Balick, Esquire; John G. Day, Esquire and Tiffany Geyer
Lydon, Esquire of ASHBY & GEDDES, Wilmington, Delaware.

Attorneys for Defendants.

MEMORANDUM OPINION

July 15, 2010
Wilmington, Delaware.


Farnan, District Judge.

Pending before the Court is a Motion For Leave To File An Amended And Supplemental Complaint And Demand For Jury Trial (D.I. 394) filed by Plaintiff Sepracor Inc. Defendants Dey, L.P. and Dey, Inc. oppose the instant Motion. (D.I. 400.) For the reasons discussed, the Court will grant Plaintiff's Motion.

I. BACKGROUND

This patent infringement action was brought by Plaintiff against Defendants, alleging infringement of United States Patent Nos. 5,362,755 ("the '755 patent"); 5,547,994 ("the '994 patent"); 5,760,090 ("the '090 patent"); 5,844,002 ("the '002 patent") and 6,083,993 ("the '993 patent") (collectively the "patents-in-suit"). The patents-in-suit pertain to the use of levalbuterol hydrochloride for treating reversible obstructive airway disease, such as asthma and chronic bronchitis.

Defendants filed Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiff's product. Specifically, Defendants sought approval to market generic versions of the 3 ml dosage form and the 0.5 ml concentrated dosage form. The filing of the ANDAs for those dosages precipitated Plaintiff's initiation of multiple infringement actions, which were ultimately consolidated into the pending action.

Defendants were the first to file an ANDA for the 0.5 ml concentrated dosage and received approval to market its generic product from the FDA on March 20, 2009. Defendants began selling a generic version of the 0.5 ml concentrated dosage in September 2009. A third party was the first to file an ANDA for the 3ml dosage, which is the most prescribed dosage. As a result of an agreement between Plaintiff and the third party, a generic 3 ml dosage has not been sold, and Defendants are not eligible to sell one at this time.

Following Defendants' sale of the generic version of the 0.5 ml concentrated dosage, Plaintiff filed the instant Motion seeking to amend and supplement its complaint originally filed in Civil Action 06-604-JJF, prior to its consolidation into the pending action. By their Motion, Defendants seek to add claims for damages based on Defendants' sale of the 0.5 ml concentrated generic product, to add Defendants' parent companies Mylan Inc. and Mylan Pharmaceuticals Inc. as parties, and to add a demand for a jury trial with respect to all triable claims.¹ (D.I. 394.)

The parties briefed their respective positions on claim construction, and, on July 18, 2008, the Court conducted a Markman hearing on the disputed terms. On December 18, 2008, the Court issued a Memorandum Opinion construing the disputed terms.

¹ The original Complaint sought only equitable relief.

(See D.I. 311.) A Pretrial Conference was scheduled for September 15, 2009, but cancelled by the Court at the request of the parties.

II. LEGAL STANDARD FOR AMENDMENT OF THE PLEADINGS

"After amending once or after an answer has been filed, the plaintiff may amend only with leave of the court or the written consent of the opposing party." Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000) (citing Fed. R. Civ. P. 15(a)). The decision to grant leave to amend lies within the discretion of the court, Foman v. Davis, 371 U.S. 178, 182 (1962); however, leave to amend should be freely given when justice requires. Fed. R. Civ. P. 15(a)(2). The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities. Dole v. Arco Chem. Co., 921 F.2d 484, 487 (3d Cir. 1990). Thus, leave to amend should ordinarily be permitted absent a showing of undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by previously allowed amendments, undue prejudice to the opposing party, or futility of the amendment. Foman, 371 U.S. at 182.

III. DISCUSSION

Defendants do not oppose allowing an amendment to add new claims related to the sale of the concentrated generic product. (D.I. 400 at 1.). However, Defendants oppose an amendment that

would allow Defendants' parent companies to be added as parties to this litigation. In addition, in light of the amended claims related to the sale of the generic product, the parties dispute whether bifurcation of the claims is warranted and whether Plaintiff's request for a jury trial covers all of the asserted claims.

A. Plaintiff's Request To Add Defendants' Parent Companies As Parties

By its Motion, Plaintiffs request the Court to add Defendants' parent companies, Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"), as parties to this action. Mylan was not added as a party when this suit was originally brought by Plaintiff. However, since that time, Defendants have been acquired by Mylan, and Plaintiff contends that Mylan participated in the launch of Defendants' 0.5 ml concentrated generic product into the marketplace. (D.I. 396 at 2.)

In response, Defendants contend that Plaintiff should not be permitted to add Mylan because doing so would necessarily lead to new discovery and substantial delay in this litigation. (D.I. 400 at 14.) Defendants further contend that an attempt to add Mylan is untimely, because Mylan could have been added as a party at the time it acquired Defendants. (Id. at 15.)

After reviewing the parties arguments in light of the applicable legal principles, the Court concludes that Plaintiff

may add Mylan as a party to the instant action based on its involvement in the sale and distribution of the generic 0.5 ml concentrated product. The sale of the product did not occur until September 2009, and Plaintiff's Motion To Amend was filed approximately one month later. Therefore, the Court finds no evidence of undue delay, dilatory motive or bad faith on Plaintiff's part in bringing the Motion To Amend. In addition, the Court is not persuaded that the addition of Mylan will unduly prejudice Defendants. While further discovery may be needed regarding Mylan, such discovery will be limited in scope to the sale and distribution of the generic product, and therefore, the Court is not persuaded that the need for additional discovery provides a valid justification for denying the Motion To Amend. Accordingly, the Court will grant Plaintiffs' Motion To Amend the Complaint to add the Mylan Defendants.

B. Defendants' Request For Bifurcation Of Liability And Damages

In light of the proffered amendments and the additional discovery that will be required as a result of these amendments, Defendants request the Court to bifurcate the liability claims which concern both the 3 ml and 0.5 ml dosages, from the damages claims which concern only the 0.5 ml dosage. Defendants contend that the liability claims are presently ready for trial, and therefore, the Court should conduct a bench trial on the liability issues and a subsequent jury trial on the damage

issues. Because a damages trial may not be needed, depending on the outcome of the liability trial, Defendants contend that bifurcation will promote efficiency and avoid delay and expense. (D.I. 400 at 8-11.) Plaintiffs contend that bifurcation will not be efficient, because there is a high likelihood of overlap in the evidence needed for both trials. (D.I. 404 at 5.)

The standard for bifurcation is established in Fed. R. Civ. P. 42(b) and is well stated in Ciena Corp.:

Under Rule 42(b) a district court has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management. . . . Courts, when exercising their broad discretion to bifurcate issues for trial under Rule 42(b), should consider whether bifurcation will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case. In deciding whether one trial or separate trials will best serve the above factors the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation.

Ciena Corp. v. Corvis Corp., 210 F.R.D. 519, 521 (D. Del. 2002) (internal citation omitted); see also Enzo Life Sciences, Inc. v. Digene Corp., Civ. No. 02-212-JJF, 2003 U.S. Dist. LEXIS 10202 (D. Del. June 10, 2003). Although the Court has discretion in deciding whether or not to bifurcate a case, bifurcation "remains the exception rather than the rule." Spinturf, Inc. v. Southwest Rec. Indus., Civ. No. 01-7158, 2004 U.S. Dist. LEXIS 785, *4-5 (E.D. Pa. Jan 15, 2004) (citing Real v. Bunn-O-Matic Corp., 195 F.R.D. 618, 620 (N.D. Ill. 2000)). The party moving for bifurcation has the burden of establishing that it is

appropriate. See Id. at *4; see also Princeton Biochemicals, Inc. v. Beckman Instruments, Inc., 180 F.R.D. 254, 256 (1997 D.N.J.); Spectra-Hysics Lasers, Inc. v. Uniphase Corp., 144 F.R.D. 99, 101 (N.D. Cal. 1992).

The Court concludes that bifurcation is not warranted in this action. As the Court has stated, the limited discovery needed for the amended claims will not cause undue delays, and the Court is not persuaded that this action is so complex that bifurcation is necessary to avoid potential confusion. In addition, the Court concludes that the potential for overlap in the presentation of the evidence weighs against bifurcation. Accordingly, the Court concludes that the interests of the parties and the Court will be best served by trying this case in a single proceeding, and therefore, the Court will deny Defendants' request for bifurcation.

C. The Right To A Jury Trial

In light of the Court's conclusion that bifurcation is not warranted, the claims are no longer exclusively equitable in nature. Accordingly, the Court concludes that a jury trial is appropriate on the issues of patent infringement, validity and damages.² See e.g., Minnesota Mining & Mfg. Co. v. Alphapharm

² The Court notes that Defendants maintain an inequitable conduct counterclaim (D.I. 60), but the parties have not mentioned this counterclaim in the context of the pending motions. Consistent with the Court's practice in other patent cases, the Court will hear the evidence related to inequitable

Pty. Ltd., 2002 WL 1352426, *3 (D. Minn. Mar. 20, 2002); Herman v. William Brooks Shoe Co., 1998 WL 832609, *3 (S.D.N.Y. Dec. 1, 1998).

IV. CONCLUSION

For the reasons discussed, the Court concludes that Plaintiff Sepracor Inc.'s Motion For Leave To File An Amended And Supplemental Complaint And Demand For Jury Trial (D.I. 394) will be granted, and Defendants' request for bifurcation will be denied.

An appropriate order will be entered.

conduct outside the presence of the jury.